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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/292,053	Reff et al
Examiner	**Group Art Unit**
Marianne DiBrino	1644

X Responsive to communication(s) filed on May 30, 2000

This action is **FINAL.**

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

X Claim(s) 1-37 is/are pending in the applicat

Of the above, claim(s) 1-25, 36, and 37 is/are withdrawn from consideration

Claim(s) _____ is/are allowed.

X Claim(s) 26-35 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

X Notice of References Cited, PTO-892

X Information Disclosure Statement(s), PTO-1449, Paper No(s). 4 filed 4/14/99

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

Notice to Comply with Sequence Rules

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reasons set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

The following procedure is to be used for cases that contain the same sequence disclosure as the parent. The applicant need not submit a new computer readable form of the Sequence Listing for this divisional application. However, (1) the specification must contain a paper copy of the Sequence Listing, (2) applicant must request in writing that the CRF in the parent case be used to prepare a file for the offspring and (3) applicant must submit a statement that the paper copy of the Sequence Listing in the offspring is identical to the computer readable form submitted in the parent case.

It is valid to use this approach to bring sequences into continuation, divisional or CIPs as long as there are no new sequences. Applicants also need to list the appropriate SEQ ID NO after any sequence that appears in the specification.

Applicant is required to fulfill these requirements. Applicant is requested to return a copy of the attached Notice to Comply with the response.

2. Applicant's election of Group II, claims 26-37 and the species 6G5 antibody with traverse in Paper No. 7 filed 5/30/00 is acknowledged. The traversal is on the grounds that a search of the Invention of Group II would overlap a search of the Invention of Group I. Further traversal is on the grounds that the invention is generic in nature, there should be no need to restrict the claims to any particular anti-CD23 antibody, and that no such requirement was made in a parent application.

Regarding undue burden, the M.P.E.P. § 803 (July 1998) states that: "For purposes of the initial requirement, a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search". The restriction requirement between Groups I and II enunciated in the previous Office Action meets this criterion and therefore establishes that serious burden is placed on the Examiner by the examinational Groups.

The requirement is still deemed proper and is therefore made FINAL.

Upon reconsideration, the prior art search has been extended to cover the anti-human CD23

monoclonal antibodies in a method of treating or preventing an allergic disorder in claims 26-35.

3. Claims 1-25 and 36-37 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention and species.

Claims 26-35 are presently being examined.

The invention being examined in this application is a method of treating or preventing an allergic disorder using anti-human CD23 monoclonal antibodies and pharmaceutical compositions thereof.

4. The documents listed on IDS filed 4/14/99 that are crossed out have not been considered by the Examiner because they were not submitted by Applicant.

5. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 34 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that the 5E8, 6G5 and 2C8 antibodies are required to practice the claimed invention. As required elements, they must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If they are not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the pertinent cell lines / hybridomas which produce these antibodies. See 37 CFR 1.801-1.809.

In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

NOTE THE CURRENT ATCC DEPOSITORY ADDRESS:
American Type Culture Collection, 10801 University Boulevard, Manassas, VA 20110-2209.

If the original deposit is made after the effective filing date of an application for patent, the applicant should promptly submit a verified statement from a person in a position to corroborate the fact, and should state, that the biological material which is deposited is a biological material specifically identified in the application as filed, except if the person is an attorney or agent registered to practice before the Office, in which the case the statement need not be verified. See MPEP 1.804(b).

Applicant may overcome this rejection by reciting specific variable region SEQ ID NOS in the claims instead of the antibody.

7. Claims 26-35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating or preventing an IgE-mediated immune allergy response with anti-CD23 monoclonal antibodies (mAbs), does not reasonably provide enablement for treating or preventing any autoimmune or inflammatory disorder with the anti-CD23 mAbs of the instant application.

The specification does not disclose how to use the instant invention for the treatment of autoimmune diseases or inflammatory responses in vivo in humans. The claimed methods encompass methods of treatment of a patient suffering from any autoimmune disease or any inflammatory response. The specification has not enabled the breadth of the claimed invention in view of the teachings of the specification because the claims encompass methods for the treatment or prevention of said diseases in vivo in humans and also encompass the same methods used prophylactically. The state of the art is such that it is unpredictable in the absence of appropriate evidence whether the claimed compositions can be used for treatment or prevention of said diseases in humans. The specification discloses no working examples with regards to the use of the instant invention for the treatment or prevention of said diseases in vivo in humans.

The state of the art is such that it is unpredictable in the absence of appropriate evidence whether the claimed compositions can be used for treatment or prevention of any autoimmune disease or any inflammatory disorder. The specification discloses no working examples with regards to the use of the instant invention for the treatment or prevention of disease in vivo in humans. In addition, evidentiary reference U.S. Patent NO. 5,736,137 discloses that in vitro functional assays cannot inherently predict the in vivo capability of a chimeric antibody to destroy or deplete target cells expressing a specific antigen. "Therefore, the potential therapeutic efficacy of chimeric antibody can only truly be assessed by in vivo experimentation" (column 4, line 67 and column 5, lines 1-12).

The instant application discloses (on page 81 and continuing through page 84) a multitude of disorders that allegedly can be treated by administration, including transplant rejection (page 83, 4th line from bottom). There is no disclosure in the instant application for treating or

preventing any disease with autoimmune or inflammatory response with the composition of the invention.

There is insufficient guidance in the specification as to how to practice the method of the instant invention. Undue experimentation would be required of one skilled in the art to practice the instant invention using the teaching of the specification alone. See Ex parte Forman, 230 USPQ 546, BPAI, 1986.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 34 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

> Claim 34 is indefinite in the recitation of 5E8, 6G5 and 2C8 because the recitation is of the designation for a monoclonal antibody in the absence of specific reference to a deposited hybridoma accession numbers.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 26, 28-33 and 35 are rejected under 35 U.S.C. 102(a) as being anticipated by Bonnefoy et al (WO 96/12741) as evidenced by Saxon et al (J. Immunol. Vol. 147 (11), 1991, pp 4000-4006).

Bonnefoy et al discloses a monoclonal humanized anti-CD23 antibody with a rodent antigen binding portion and which may be either an IgG1 or an IgG3 and pharmaceutical composition thereof (especially page 4, lines 1-3 and lines 15-19, page 5, lines 4-11 and 25-27 and claims 11-15) and a method for treating allergic diseases using said antibody, including blocking an IgE immune response (especially page 8, lines 20-22 and claims 1-4). It is an inherent property of anti-CD23 antibodies to inhibit IgE expression as evidenced by Saxon et al (especially Abstract). Claim 33 is included because the ability to inhibit IgE expression in vivo is an inherent property of said antibodies because they have this property in vitro.

13. Claims 26-33 and 35 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Bonnefoy et al (WO 96/12741, Applicant's IDS reference) in view of Saxon et al (J. Immunol. Vol. 147 (11), 1991, pp 4000-4006, Applicant's IDS reference) and Newman et al (U.S. Patent No. 5,658, 570).

Bonnefoy et al discloses a monoclonal humanized anti-CD23 antibody with a rodent antigen binding portion and which may be either an IgG1 or an IgG3 and pharmaceutical composition thereof (especially page 4, lines 1-3 and lines 15-19, page 5, lines 4-11 and 25-27 and claims 11-15) and a method for treating allergic disease using said antibody, including blocking an IgE immune response (especially page 8, lines 20-22 and claims 1-4).

Bonnefoy et al do not disclose a method of treating an allergic disease using an anti-CD23 antibody comprising a primate antigen binding region.

Saxon et al teach that anti-CD23 antibodies inhibit IgE expression (especially Abstract).

Newman et al disclose chimeric or humanized anti-CD23 antibodies which comprise a human constant region of IgG isotype and a primate antigen binding region (especially claims 1-8 and column 8, lines 52-53) and a method of administering a therapeutically effective amount of said antibody (especially also column 6, lines 1-8) . Newman et al also disclose that non-human primate antibodies are expected to be an improvement over mouse monoclonal antibodies for in vivo human therapy (especially column 1, lines 45-51). Newman et al further disclose that chimeric mouse-human antibodies elicit antibody production when used in humans (especially column 1, lines 40-44).

It would have been prima facie obvious at the time the invention was made to have used the anti-CD23 antibody of Newman et al in the method of Bonnefoy et al. One of ordinary skill in the art at the time the invention was made would have been motivated to do this in order to

treat an allergic disorder in a human with reduced side effects from immunogenicity of the anti-CD23 antibody. Claim 33 is included because the ability to inhibit IgE expression in vivo is an expected property of said antibodies because they have this property in vitro.

14. Claims 26-35 are objected to as being dependent upon non-elected claims. Applicant is required to rewrite claims in independent form including all of the limitations of the base claim and any intervening claims.

15. Claim 34 appears to be free of the prior art.

16. The references cross-out in Applicant's IDS have not been considered because they can not be located in the parent application. It would expedite prosecution if the Applicant would provide said references.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne DiBrino whose telephone number is (703) 308-0061. The examiner can normally be reached Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Marianne DiBrino, Ph.D.
Patent Examiner
Group 1640
Technology Center 1600
June 19, 2000

Christina Chan
CHRISTINA Y. CHAN
SUPERVISORY PATENT EXAMINER
GROUP ~~1800~~ 1600